PART 233

PHARMACEUTICAL AND COSMETIC MANUFACTURING PROCESSES

(Statutory authority: Environmental Conservation Law, §§ 3-0301, 19-0301, 19-0303)

Historical Note

Part (§§ 233.1-233.8) renum. Part 390, Title 9, filed Sept. 1971; new (§§ 233.1-233.6) filed April 10, 1981; amds. filed: March 5, 1993 eff. 30 days after filing; April 2, 1993 eff. April 4, 1993. Amended Part title.

Section 233.1 Applicability and compliance. (a) The owner or operator of a pharmaceutical or cosmetic manufacturing process which meets the applicability criteria of this Part must obtain a permit to construct or a certificate to operate prior to commencing construction and/or operation of the process, as required by Part 201 of this Title, which includes the method or methods which will be used to comply with the control requirements of this Part.

(b) The owner or operator of a pharmaceutical or cosmetic manufacturing process at facilities in the New York City metropolitan area must comply with this Part according to the following schedule:

(1) Synthesized pharmaceutical manufacturing processes which were constructed on or before May 10, 1981 at any facility compliance must have demonstrated compliance with this Part by December 1, 1982.

(2) Synthesized pharmaceutical manufacturing processes which were constructed after May 10, 1981 must demonstrate compliance with this Part through the submission of an application for a permit to construct or a certificate to operate containing the method or methods which will be used to comply with the control requirements, prior to commencing construction.

(3) The owner or operator of all other pharmaceutical manufacturing processes not regulated by paragraphs (1) and (2) of this subdivision or cosmetic manufacturing processes, at any facility with annual potential to emit volatile organic compounds from all sources regardless of process type, but excluding combustion installations, that equal or exceed 25 tons must:

(i) submit a compliance plan to the Department of Environmental Conservation by November 15, 1993, which contains a schedule of the steps necessary for the facility to achieve compliance with this Part or reduce the facility's annual potential to emit below the applicability criteria and the dates by which each step will be completed;

(ii) be in compliance with this Part or have permits modified to limit the facility's annual potential to emit below the applicability criteria by June 1, 1995; and

(iii) maintain the VOC control requirements and compliance schedule included in any permit, regulation, rule, administrative order, or any judicial order, until compliance with the provisions of this Part is demonstrated to the satisfaction of the commissioner.

(c) The owner or operator of a pharmaceutical or cosmetic manufacturing process at facilities in the Lower Orange County metropolitan area must comply with this Part according to the following schedule:

(1) Synthesized pharmaceutical manufacturing processes which were constructed on or before May 10, 1981 at any facility for which the annual potential to emit volatile

organic compounds from all sources regardless of process type, but excluding combustion installations, equal or exceed 100 tons must have demonstrated compliance with this Part by December 1, 1982.

(2) Synthesized pharmaceutical manufacturing processes which were constructed after May 10, 1981 at any facility for which the annual potential to emit volatile organic compounds from all sources regardless of process type, but excluding combustion installations, equal or exceed 100 tons must demonstrate compliance, through the submission of an application for permit to construct or a certificate to operate containing the method or methods which will be used to comply with the control requirements, prior to commencing construction.

(3) Synthesized pharmaceutical manufacturing processes at any facility for which the annual potential to emit volatile organic compounds from all sources regardless of process type, but excluding combustion installations, equal or exceed 10 tons must:

(i) submit a compliance plan to the Department of Environmental Conservation by November 15, 1993, which contains a schedule of the steps necessary for the facility to achieve compliance with this Part or reduce the facility's annual potential to emit below the applicability criteria and the dates by which each step will be completed;

(ii) be in compliance with this Part or have permits modified to limit the facility's annual potential to emit below the applicability criteria by June 1, 1995; and

(iii) maintain the VOC control requirements and compliance schedule included in any permit, regulation, rule, administrative order, or any judicial order until compliance with the provisions of this Part is demonstrated to the satisfaction of the commissioner.

(4) The owner or operator of all other pharmaceutical manufacturing processes not regulated by paragraphs (1), (2), and (3) of this subdivision or cosmetic manufacturing processes at any facility for which the annual potential to emit volatile organic compounds from all sources regardless of process type, but excluding combustion installations, equal or exceed 25 tons must:

(i) submit a compliance plan to the Department of Environmental Conservation by November 15, 1993, which contains a schedule of the steps necessary for the facility to achieve compliance with this Part or reduce the facility's annual potential to emit below the applicability criteria and the dates by which each step will be completed;

(ii) be in compliance with this Part or have permits modified to limit the facility's annual potential to emit below the applicability criteria by June 1, 1995; and

(iii) maintain the VOC control requirements and compliance schedule included in any permit, regulation, rule, administrative order, or any judicial order until compliance with the provisions of this Part is demonstrated to the satisfaction of the commissioner.

(d) The owner or operator of a pharmaceutical or cosmetic manufacturing process at any facility located outside the New York City metropolitan area and the Lower Orange County metropolitan area must comply with this Part according to the following schedule:

(1) Synthesized pharmaceutical manufacturing processes which were constructed on or before May 10, 1981 at any facility located in the counties of Albany, Cayuga, Columbia, Dutchess, Erie, Genesee, Greene, Livingston, Monroe, Niagara, Onondaga, Orange (excluding the towns of Blooming Grove, Chester, Highlands, Monroe, Tuxedo, Warwick, and Woodbury), Ontario, Orleans, Putnam, Rensselaer, Saratoga (limited

to the towns of Clifton Park and Halfmoon, the city of Mechanicville, and the town and village of Waterford), Schenectady, Seneca, Ulster, Wayne, Wyoming or Yates for which the annual potential to emit volatile organic compounds equal or exceed 100 tons must have demonstrated compliance with this Part by December 1, 1982.

(2) Synthesized pharmaceutical manufacturing processes at any facility which was constructed after May 10, 1981 for which the annual potential to emit volatile organic compounds from all sources regardless of process type, but excluding combustion installations, at the facility equal or exceed 100 tons per year must have demonstrated compliance with this Part prior to commencing construction.

(3) Synthesized pharmaceutical manufacturing processes at any facility for which the annual potential to emit volatile organic compounds from all sources regardless of process type, but excluding combustion installations, equal or exceed 10 tons must:

(i) submit a compliance plan to the Department of Environmental Conservation by November 15, 1993, which contains a schedule of the steps necessary for the facility to achieve compliance with this Part or reduce the facility's annual potential to emit below the applicability criteria and the dates by which each step will be completed;

(ii) be in compliance with this Part or have permits modified to limit the facility's annual potential to emit below the applicability criteria by June 1, 1995; and

(iii) maintain the VOC control requirements and compliance schedule included in any permit, regulation, rule, administrative order, or any judicial order until compliance with the provisions of this Part is demonstrated to the satisfaction of the commissioner.

(4) All other pharmaceutical manufacturing processes not regulated by paragraphs (1), (2), and (3) of this subdivision or cosmetic manufacturing processes at any facility for which the annual potential to emit volatile organic compounds from all sources regardless of process type, but excluding combustion installations, equal or exceed 50 tons must:

(i) submit a compliance plan to the Department of Environmental Conservation by November 15, 1993, which contains a schedule of the steps necessary for the facility to achieve compliance with this Part or reduce the facility's annual potential to emit below the applicability criteria and the dates by which each step will be completed;

(ii) be in compliance with this Part or have permits modified to limit the facility's annual potential to emit below the applicability criteria by June 1, 1995; and

(iii) maintain the VOC control requirements and compliance schedule included in any permit, regulation, rule, administrative order, or any judicial order until compliance with the provisions of this Part is demonstrated to the satisfaction of the commissioner.

(e) This Part previously contained a facility-wide emission reduction (bubble) plan involving synthesized pharmaceutical manufacturing processes covered by the provisions of this Part. Any owner or operator of a facility which has operated in accordance with a facility-wide emission reduction plan approved by the commissioner must:

(1) submit a compliance plan to the Department of Environmental Conservation by November 15, 1993, which contains a schedule of the steps necessary for the facility to achieve compliance with this Part or reduce the facility's annual potential to emit below the applicability criteria and the dates by which each step will be completed;

(2) be in compliance with this Part or have permits modified to limit the facility's annual potential to emit below the applicability criteria by June 1, 1995; and

(3) maintain the VOC control requirements and compliance schedule included in any permit, regulation, rule administrative order, or any judicial order until compliance with the provisions of this Part is demonstrated to the satisfaction of the commissioner.

(f) Any process that is subject to the provisions of this Part will remain subject to these provisions even if the emissions of volatile organic compounds from the facility later fall below the applicability criteria.

(g) This Part shall not apply to the following pharmaceutical and cosmetic manufacturing processes and sources:

(1) the manufacture of pharmaceutical or cosmetic products for study rather than eventual sale at facilities which have annual potential to emit volatile organic compounds from all sources, regardless of process type but excluding combustion installations, which are less than 25 tons in the New York City metropolitan area and the Lower Orange County metropolitan area, or which are less than 50 tons outside those areas of the State; and

(2) any reactor, extractor, distillation operation, crystallizer, centrifuge or vacuum dryer which has an emission rate potential for volatile organic compounds equal to or less than 15 pounds per day.

(h) Pharmaceutical and cosmetic manufacturing processes which are not regulated under this Part must comply with all other applicable Parts of this Subchapter.

Historical Note

Sec. amd. filed May 5, 1971; renum. 390.1, Title 9, filed Sept. 1971; new filed April 10, 1981; repealed, new filed: March 5, 1993 eff. 30 days after filing; April 2, 1993 eff. April 4, 1993.

233.2 Definitions. (a) For the purposes of this Part, the general definitions and requirements of Part 200 of this Title shall apply.

(b) For the purpose of this Part, the following definitions shall apply:

(1) *Annual.* Refers to a period of time based upon a calendar year commencing January 1st and terminating midnight December 31st.

(2) *Condenser.* A device which cools a gas stream to a temperature at which all or some of the vaporized volatile organic compounds in the gas stream will condense and will be removed.

(3) *Cosmetic manufacturing process.* Any process producing or blending chemicals for use in cosmetic products and/or manufacturing cosmetic products by chemical processes. Cosmetic products include, but are not limited to, colognes, perfumes, and nail polish.

(4) *Control system.* Any control devices, including, but not limited to condensers, which are designed and operated to reduce the quantity of contamiants, including but not limited to volatile organic compounds emitted to the atmosphere.

(5) *In-process tank.* Containers used for mixing, blending, heating, reacting, holding, crystallizing, evaporating or cleaning operations in the manufacture of pharmaceuticals.

(6) *Lower Orange County metropolitan area.* The area including the towns of Blooming Grove, Chester, Highlands, Monroe, Tuxedo, Warwick and Woodbury.

(7) *New York City metropolitan area.* All of the city of New York, and Nassau, Suffolk, Westchester and Rockland Counties.

(8) *Pharmaceutical manufacturing process.* Any process involving the manufacture of pharmaceutical products and intermediates, including but not limited to, the following operations:

(i) the manufacture of pharmaceutical products and intermediates by chemical synthesis;

(ii) the production and separation of medicinal chemicals including, but not limited to, antibiotics and vitamins from microorganisms;

(iii) the manufacture of botanical and biological products by the extraction of organic chemicals from vegetative materials or animal tissues; or

(iv) the formulation of pharmaceuticals into various dosage forms including, but not limited to, tablets, capsules, injectable solutions or ointments, that are to be taken by the patient immediately and in accurate amounts.

(9) *Potential to emit.* The maximum capacity of an air contamination source to emit any air contaminant under its physical and operational design. Any physical or operational limitation on the capacity of the facility or air contamination source to emit any air contaminant, including air pollution control equipment and/or restriction on the hours of operation, or on the type or amount of material combusted, stored, or processed shall be treated as part of the design only if the limitation is contained in enforceable permit conditions. Fugitive emissions, to the extent that they are quantifiable, are included in determining the potential to emit.

(10) *Production equipment exhaust system.* A device for collecting and directing volatile organic compound fugitive emissions from reactor openings, centrifuge openings, and other vessel openings out of the work area for the purpose of protecting workers from exposure and/or to reduce vapor concentrations below the lower explosive limit.

(11) *Reactor.* A vat or vessel, which may be jacketed to permit temperature control, designed to control chemical reactions.

(12) *Separation operation.* A process that separates a mixture of compounds, including liquids and/or solids into two or more components. Specific mechanisms include extraction, centrifugation, filtration and crystallization.

(13) *Synthesized pharmaceutical manufacturing process.* Any process involving the manufacture of pharmaceutical products and intermediates by chemical synthesis. The production and recovery of materials produced via fermentation, extraction of organic chemicals from vegetative materials or animal tissues, and formulation and packaging of the product are not considered to be synthesized pharmaceutical manufacturing processes.

Historical Note

Sec. amd. filed Nov. 29, 1967; renum. 390.2, Title 9, filed Sept. 1971; new filed April 10, 1981; amds. filed: March 5, 1993 eff. 30 days after filing; April 2, 1993 eff. April 4, 1993.

233.3 Control requirements. (a) *Process equipment requirements.* The owner or operator of a pharmaceutical or cosmetic manufacturing process subject to this Part must control the volatile organic compound emissions from reactors, extractors, distillation operations, crystallizers, centrifuges, and vacuum dryers which have an emission rate potential of more than 15 pounds per day as follows:

(1) When surface condensers are used, the condenser outlet gas temperature must not exceed the allowable temperature limit described for each associated vapor pressure in the Table 1.

Table 1

VOC vapor pressure at 20°C (psi)	*Allowable condenser outlet gas temperature (°C)*
> 5.8	- 25
> 2.9	- 15
> 1.5	0
> 1.0	10
> 0.5	25

(2) If the operation of a condenser at the exit temperature specified above results in freezing and consequent plugging of the condenser, the allowable exit temperature may be raised to a maximum of 2°C above the freezing point of the volatile organic compound.

(3) In cases where the condenser outlet gas temperature is not readily measurable due to negligible gas flow rate, the temperature of the condenser coolant may be used in lieu of condenser outlet gas temperature as long as the temperature of the condenser coolant does not exceed the allowable condenser outlet gas temperature shown in Table 1.

(b) *Air dryer and production equipment exhaust system requirements.* Except as provided under subdivision (a) of this section, the owner or operator of a pharmaceutical or cosmetic manufacturing process subject to this Part must not operate, cause, allow or permit the operation of any air dryer or production exhaust system which conducts fugitive volatile organic compounds from a work area unless the emissions to the outdoor atmosphere are controlled as follows:

(1) for air dryers and production equipment exhaust systems with an emission rate potential of volatile organic compounds of 330 pounds per day or more, 90 percent control is required;

(2) for air dryers and production equipment exhaust systems with an emission rate potential of volatile organic compounds of less than 330 pounds per day, an emission reduction to 33 pounds per day is required.

(c) *VOC transfer requirements.* For the transfer of volatile organic compounds with vapor pressures greater than 4.1 psi at 20°C from trucks or railcars to storage tanks with capacities greater than 2,000 gallons, other than tanks with floating roofs, vapor recovery or equivalent controls, a vapor balance system or equivalent control that provides at least 90.0 percent control of the volatile organic compound emissions is required.

(d) *Storage tank requirements.* For all storage tanks that store volatile organic compounds with vapor pressures greater than 1.5 psi at 20°C, pressure/vacuum conservation vents set at 0.03 psi must be installed, unless more effective control equipment is used.

(e) *Centrifuge and filter requirements.* All centrifuges containing volatile organic compounds, rotary vacuum filters processing volatile organic compounds and any other filters having an exposes liquid surface where the liquid contains volatile organic compounds and exerts a total vapor pressure of 0.5 psi or more at 20°C must be enclosed unless production, sampling, maintenance, or inspection procedures require operator access.

(f) *In-process tank requirements.* For in-process tanks containing a volatile organic compound, covers must be installed on openings to these tanks. Tank openings must remain covered unless production, sampling, maintenance, or inspection procedures require operator access.

(g) *Leak requirements.* All leaks from which a liquid containing volatile organic compounds can be observed running or dripping must be repaired the first time the

equipment is off-line for a period of time long enough to complete the repair, but not later than 15 days after the leak is discovered. If the leaking component cannot be repaired until the process is shut down, and a shut down cannot be done within the 15 days after the leak is detected, the leaking component must then be repaired before the process is restarted.

(h) (1) The commissioner may allow processes subject to this Part to operate with a lesser degree of control than what is required per subdivisions (a)-(g) of this section provided that a process specific reasonably available control technology (RACT) demonstration has been made to the satisfaction of the commissioner. Process specific RACT demonstrations must be submitted with the application for a permit to construct, a certificate to operate, or renewal of a certificate to operate for an existing source under the provisions of Part 201 of this Title. Such process specific RACT demonstrations must be submitted to the United States Environmental Protection Agency as a revision to the State Implementation Plan and must address the technical and economic feasibility of:

(i) utilizing demonstrated and proven emission control technologies which would achieve the degree of control required in subdivision (a)-(g) of this section;

(ii) utilizing demonstrated and proven emission control technologies which would not achieve the degree of control required in subdivision (a)-(g) of this section;

(iii) utilizing demonstrated and proven production modification methods which would result in real, documented, and enforceable reductions in the volatile organic compound emissions from the process.

(2) Facilities with processes subject to this Part with an annual potential to emit less than five tons of volatile organic compounds will only be required to comply with subparagraphs (1)(i) and (1)(iii) of this subdivision in order to demonstrate that a lesser degree of control is RACT for these processes.

(3) The commissioner may allow sources which use natural gas fired afterburners as control devices for processes subject to this Part, to shut down these natural gas fired afterburners from November 1st through March 31st for the purposes of natural gas conservation, provided that the commissioner has determined that this action will not jeopardize air quality. Such evidence must be submitted with the application for a permit to construct, a certificate, or renewal of a certificate to operate for an existing source under the provisions of Part 201 of this Title.

Historical Note

Sec. renum. 390.3, Title 9, filed Sept. 1971; new filed April 10, 1981; amds. filed: March 5, 1993 eff. 30 days after filing; April 2, 1993 eff. April 4, 1993.

233.4 Testing and monitoring. (a) The owner and/or operator of a pharmaceutical or cosmetic manufacturing process must follow notification requirements, protocol requirements and test procedures of Part 202 of this Title for testing and monitoring of these processes.

(b) The test procedures to determine compliance must be approved by the commissioner and be consistent with appendix A of part 60 of title 40 of the *Code of Federal Regulations* (see table 1, section 200.9 of this Title). Depending upon conditions at a test site, one of the following test methods from appendix A of 40 CFR 60 (see table 1, section 200.9 of this Title) must be used to determine volatile organic compound (VOC) concentrations of a gas stream at the inlet and outlet of a control device:

(1) Method 18, Measurement of Gaseous Organic Compound Emissions by Gas Chromatography.

(2) Method 25, Determination of Total Gaseous Organic Emissions as Carbon.

(3) Method 25A, Determination of Total Gaseous Organic Concentration Using a Flame Ionization Analyzer.

(4) Methods not listed above must be approved in advance by the department's representative and the United States Environmental Protection Agency.

(c) Any facility which is not subject to the control requirements of this Part because its annual potential to emit volatile organic compounds are below the applicability levels, must maintain records in a format acceptable to the commissioner's representative that verify the facility's annual potential to emit VOC. Upon request, these records must be submitted to the department.

(d) If an air cleaning device is used, continuous monitors for the following parameters must be installed, periodically calibrated, and operated at all times that the associated process equipment and control equipment are operating:

(1) an exhaust gas temperature of all incinerators;

(2) temperature rise across a catalytic incinerator bed;

(3) breakthrough of volatile organic compounds on a carbon adsorption unit; and

(4) outlet gas temperature of a refrigerated condenser;

(5) temperature of nonrefrigerated condenser coolant supply system; or

(6) any other continuous monitoring or recording device required by the commissioner for the purpose of demonstrating compliance with the control requirements of this Part.

(e) Each monitor must be equipped with a recording device.

(f) Each monitor must be calibrated quarterly.

(g) Each monitor must operate at all times while the associated control equipment is operating.

Historical Note

Sec. amds. filed Feb. 7, 1964; July 22, 1966; March 26, 1971; renum. 390.4, Title 9, filed Sept. 1971; new filed April 10, 1981; repealed, new filed: March 5, 1993 eff. 30 days after filing; April 2, 1993 eff. April 4, 1993.

233.5 Recordkeeping. (a) The owner or operator of a pharmaceutical or cosmetic manufacturing process subject to this Part must maintain the following records at the facility for a period of five years:

(1) parameters listed in section 233.4(c) and (d) must be recorded and;

(2) the vapor pressure of the volatile organic compound at 20°C being controlled must be recorded for every process.

(b) For any leak subject to section 233.3(g), which cannot be readily repaired within one day after detection, the following records must be kept:

(1) the name of the leaking equipment;

(2) the date and time the leak is detected;

(3) the action taken to repair the leak; and

(4) the date and time the leak is repaired.

Historical Note

Sec. renum. 390.5, Title 9, filed Sept. 1971; new filed April 10, 1981; repealed, new filed: March 5, 1993 eff. 30 days after filing; April 2, 1993 eff. April 4, 1993.

233.6

Historical Note

Sec. renum. 390.6, Title 9, filed Sept. 1971; new filed April 10, 1981; repealed, filed: March 5, 1993 eff. 30 days after filing; April 2, 1993 eff. April 4, 1993.

233.7-233.8

Historical Note

Secs. renum. 390.7-390.8, Title 9, filed Sept. 1971.

233.9

Historical Note

Sec. repealed, filed Sept. 8, 1966.